

REMARKS

This paper is responsive to the Final Office Action mailed December 3, 2007 (the “Office Action”). A Request for Continued Examination and the appropriate fee is enclosed.

Claims 1 – 7, 14, 15, 32, 34, 37-39, 46-48, and 84 – 85 are under consideration in this application.

Claims 21 – 23 have been rejected under 35 U.S.C. §112 because it is not clear whether the parent or progeny phage are dissociated. It is intended that whatever phage are in the sample at the time of disassociation are dissociated. This will include the progeny bacteriophage, but also may include the parent bacteriophage if the parent bacteriophage have not been removed. Claim 21 has been amended to clarify this.

Claims 46 – 48 and 50 are rejected as being unpatentable over Takahashi et al. (WO 98/08944 as translated in U.S. Patent No. 6,322,783, hereinafter “Takahashi et al.”) in view of Mouton (U.S. Patent No. 5,789,174, hereinafter “Mouton”). This rejection is respectfully traversed. The Office Action states that the fact that the combination of Takahashi et al. and Mouton would result in a different method than that claimed is irrelevant because Mouton is used to show that it was known in the prior art to run negative control assays. First of all, the claim does not state that a negative control assay is run. The claim states that a reference assay is performed, which is very much different than a negative control assay. If bacteria are present in the sample, there will be a positive result. It is nowhere suggested in the prior art that it is possible to obtain a reliable determination of the presence or absence of a bacteria by comparing two different positive results. This is an entirely novel feature of the present application that was nowhere present in the bacteriophage art prior to this application. In fact, Mouton emphasizes that “It is to be understood that, for example, *Porphyromonas gingivalis* was used as a negative control not against its own detection assays, but against the assays of three other species, ...”. (Mouton, Col. 7, lines 26 – 29.) The fact that the USPTO must go to an art that does not even mention bacteriophage and then change what was actually done, and even then not get a similar method, shows how novel this is. Put another way, the combination of Takahashi et al. and Mouton is three modifications removed from claim 46 – 48 and 50. It is clear when so many modifications are

being made to get from the references to the claim that the Office Action is using the present application as a guide, not the prior art. This is hindsight, which is impermissible. See MPEP 2145X.A and *W.L. Gore & Associates, Inc. v. Garlock*, 220 U.S.P.Q. 303, 311-13 (Fed. Cir. 1983).

Claims 1 – 3, 7, 14, 15, 37 – 39, 84, and 85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4 – 6, and 8 – 10 of copending Application No. 11/698,673. This rejection is respectfully traversed. The present claims represent only a qualitative measurement, while the claims of the copending application represent a quantitative measurement that is not at all encompassed by the present claims. The Office Action states that the present claims require a step of waiting, which may be true, but that is not what the copending claims recite. They recite waiting for a predetermined time. Thus, none of the embodiments of the pending claims are covered by the present claims. Claims 1, 2, 4 – 6, and 8 – 10 of the copending application also require that a predetermined amount of bacteriophage be added to the sample and that the level of the bacteriophage be determined. These are three steps that are not in the present claims. Thus, the doctrine of obviousness type double patenting does not apply.

In view of the above amendments and remarks, Applicants believe the pending application is in condition for allowance. A Request For Continued Examination (RCE) and the required fee is enclosed. Applicants believe no additional fee is due with this response. However, if any additional fee is due, please charge our Deposit Account No. 50-1848, under Order No. 022116.0102PTUS from which the undersigned is authorized to draw.

Respectfully submitted,
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